UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

FILED

MAY 15 2015

U. S. DISTRICT COURT
EASTERN DISTRICT OF MO
ST. LOUIS

UNITED STATES OF AMERICA,	)
	)
Plaintiff,	)
	)
v.	) No. S1-4:13CR00300 HEA
	)
PATTERSON MEDICAL CENTER, INC.,	)
MEL E. LUCAS, D.O., and	)
ROBYN LEVY,	)
	)
Defendants.	)

INFORMATION

COUNT 1

The United States Attorney charges that:

1. At all relevant times, Mel E. Lucas was a doctor of osteopathic medicine, licensed to practice in the state of Missouri. Dr. Lucas is the owner of Patterson Medical Clinic, Inc. (Patterson Medical), located at 2175 Charbonier in Florissant, Missouri. Dr. Lucas is the only doctor practicing at Patterson Medical.

2. Dr. Lucas and Patterson Medical have been approved Medicare providers since 2001 and approved TRICARE providers since January 1, 2005. Dr. Lucas has also been a provider for several private insurance companies, including Anthem Blue Cross Blue Shield and Blue Shield of Missouri (Blue Cross).

Relevant Medicare Provisions

3. The Medicare Program is a federal health benefits program for the elderly and disabled. The United States Department of Health and Human Services (HHS), through the Centers for Medicare and Medicaid Services (CMS), administers the Medicare Program. CMS

acts through fiscal agents, which are private entities that review claims and make payments to providers for services rendered to Medicare beneficiaries.

4. Medicare providers must retain clinical records for the period of time required by state law or five years from date of discharge if there is no requirement in state law. Missouri statutes require that physicians maintain patient records for a minimum of seven years from the date when the last professional services were rendered. Thus, Missouri law mandates that the defendant and Dr. Lucas maintain all patient records for services provided from 2007 to the present.

Relevant Tricare Provisions

5. TRICARE is a federal health benefits program for military personnel and their families. TRICARE contracts with private health plans to administer benefits for medical services that take place outside military medical facilities.

6. TRICARE policies and benefits are governed by public law and federal regulation. TRICARE providers are obligated to abide by the rules, procedures, policies and program requirements as specified in the TRICARE Provider Handbook. TRICARE providers are required to maintain medical records, reflecting the condition of the patients and the services provided to patients.

7. Patterson Medical used a form (Treatment Form) to record and document the patients' condition at the time of the office visit, any physical examination conducted, the assessment/diagnosis, and the treatment provided at Patterson Medical. The Treatment Form also purportedly identified the person providing the service. While the Treatment Forms were not submitted to Medicare or TRICARE, the Treatment Form is a part of the patient medical file and

the information on the Treatment Form may affect the assessment, diagnosis, and treatment of the patient in the future.

8. Patterson Medical employed medical assistants who saw patients who came in for injections and to have their blood drawn. The medical assistants indicated on the Treatment Form the patients' vital signs and the blood draw or the injection that they gave. The medical assistants did not perform physical examinations or do assessments and diagnoses of Dr. Lucas' patients. The Treatment Forms and patient files were then left for Dr. Lucas to review when he returned to the office. In several instances, Dr. Lucas completed that portion of the Treatment Form entitled "Review of Systems, Physical Exam, Plan, and Assessment/Diagnosis" with the patient's earlier diagnosis from a previous visit even though no such exam had occurred for the current visit. Some examples of these false entries, while not exhaustive, are described below:

a. A Treatment Form dated October 1, 2008, indicates that the ear, nose, throat, and neck inspection of Patient F.W. was normal ("nml"), he/she was in "no acute distress," his/her extremities were "non-tender," and he/she was "oriented x3," when in fact the only service provided to Patient F.W. on October 1, 2008 was an injection by a medical assistant.

b. A Treatment Form dated January 13, 2010, indicates that the ear, nose, throat, and neck inspection of Patient P.M. was normal ("nml") and he/she was in "no acute distress" and was experiencing "no resp. distress, that the patient's abdomen was "soft, nontender," his/her skin was normal in color, extremities were "non-tender," and he/she was "oriented x3," when in fact the only service provided to Patient P.M. on January 13, 2010 was a blood draw by a medical assistant.

c. A Treatment Form dated May 27, 2010 indicates that the ear, nose, throat, and neck inspection of Patient K.S. was normal ("nm1") and he/she was in "no acute distress" and was experiencing "no resp. distress," when in fact the only service provided to Patient K.S. on May 27, 2010 was a B-12 injection administered by a medical assistant.

d. A November 10, 2010 Treatment Form indicates that the ear, nose, throat, neck, and pharynx inspection of Patient R.N. was normal ("nml"); and he/she was in "no acute distress" and was experiencing "no resp. distress," that Patient R.N.'s skin was a normal color, his/her extremities were "non-tender," and he/she was "oriented x 3" when in fact the only service provided to Patient R.N. on November 10, 2010 was an injection administered by a medical assistant.

9. On or about January 13, 2010, in the Eastern District of Missouri,

PATTERSON MEDICAL CENTER, INC.,

Defendant herein, in a matter involving a health care benefit program, knowingly and willfully made a writing or document knowing the same to contain materially false statements and entries in connection with the delivery of health care services, in that entries were made in the section of the Treatment Form entitled "Review of Systems, Physical Exam, Plan, and Assessment/Diagnosis" so that the document purported to represent that a physical exam had taken place on the date therein when no such exam had taken place.

All in violation of Title 18, United States Code, Sections 1035(a)(2) and 2.

COUNT 2

1. Paragraphs 1 and 2 of Count 1 are restated and incorporated as if fully set forth herein.

2. Robyn Levy is an Adult Nurse Practitioner ("A.N.P.") and has been employed at Patterson Medical since about 2003.

U.S. Food and Drug Administration

3. The United States Food and Drug Administration ("FDA") is the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et.seq. ("FDCA"). FDA's responsibilities under the FDCA include regulating the manufacture, labeling, and distribution of all drugs and drug components shipped or received in interstate commerce and foreign commerce. FDA must approve prescription drugs before the drug can be legally sold, distributed, prescribed, or dispensed in the United States. U.S.C. § 355(a).

Prescription Drugs

4. Under the FDCA, drugs include articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and articles intended to affect the structure or any function of the human body. 21 U.S.C. § 321(g)(1)(B) and (C). A drug is deemed to be a prescription drug if, because of its toxicity and other potential harmful effects, it is not safe for use except under the supervision of a practitioner licensed by law to administer the drug. 21 U.S.C. § 353(b)(1).

5. In 2007, the FDA approved Zoledronic Acid, solution, 5 mg/100 ml, under the brand name Reclast, which belongs to a class of drugs that strengthen bone and is used primarily

to treat osteoporosis. Zoledronic Acid is a prescription drug within the meaning of 21 U.S.C. § 353(b)(1) because of the drug's toxicity or other potential harmful effects. As such, only a licensed medical practitioner may lawfully prescribe or dispense Zoledronic Acid, under the brand name Reclast.

6. Zoledronic Acid is manufactured by the Novartis Corporation in Switzerland and approved by FDA for sale and use in the United States. In the United States, it can only be sold under the brand name Reclast. Aclasta, another brand name for the prescription drug Zoledronic Acid, is also manufactured by Novartis in Switzerland, but is not a brand name approved by FDA for use in the United States and may not legally be imported, prescribed, or dispensed in the United States. The chemical formula of Aclasta is identical to Reclast and is also used to treat patients with osteoporosis.

Misbranding

7. Under the authority of the FDCA, 21 U.S.C. §§ 301-399, a drug is misbranded under the FDCA if the labeling is false or misleading. 21 U.S.C. § 352(a). A drug is also misbranded if the labeling fails to bear adequate directions for use or fails to bear adequate warnings where use of the drug may be dangerous to the health of users. 21 U.S.C. §§ 352(f)(1), 352 (f)(2). A drug that does not bear a label approved by the FDA is misbranded.

8. The FDCA prohibits the receipt in interstate commerce of any drug that is misbranded and the delivery or proffered delivery thereof for pay or otherwise. 21 U.S.C. § 331(c).

Illegal Receipt of Aclasta in the United States

9. From in or about April 2009 to in or about September 2011, Patterson Medical and Dr. Lucas repeatedly purchased Aclasta online from two Canadian companies, Canada

Health Solutions and Global Health Supplies. Patterson Medical and Dr. Lucas paid about $749.00 for each bottle of Aclasta, which is several hundred dollars less than the price of a bottle of Reclast purchased in the United States.

10. Dr. Lucas used his Bank of America/American Express credit card to pay for Aclasta, which was shipped by Parcel Force Worldwide (located in the United Kingdom) to Patterson Medical.

11. In her capacity as an employee of Patterson Medical, Defendant Levy infused patients with Zoledronic Acid which was provided by Patterson Medical under the brand name Reclast and which was approved by the FDA. Defendant Levy also infused patients with Zoledronic Acid which was provided by Patterson Medical under the brand name Aclasta, but which was not approved by the FDA.

12. On or about April 10, 2013, federal agents recovered ten boxes of Aclasta from Patterson Medical. The word "Aclasta" was prominently displayed on the bottles of Aclasta. The bottles also had Italian or Turkish language on them, a clear indication that the drug was not intended for use in the United States.

13. On or before April 10, 2013, in the Eastern District of Missouri,

MEL E. LUCAS, D.O., and ROBYN LEVY,

Defendants herein, received in interstate commerce a quantity of the prescription drug Aclasta, imported from Canada, via the United Kingdom, that was misbranded within the meaning of the Food, Drug, and Cosmetic Act in that (a) the drug's labeling failed to bear adequate directions for use in that the drug's labeling was in the Turkish or Italian language, 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.5, and (b) the Aclasta came from Novartis, a foreign drug establishment located in

Switzerland, and Aclasta was not annually listed with the FDA by Novartis as one of the drugs which was being manufactured for commercial distribution in the United States.

In violation of Title 21, United States Code, Sections 331(c), 333(a)(1), 352(f), and Title 18, United States Code, Section 2.

Respectfully submitted,

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UNITED STATES OF AMERICA)
EASTERN DIVISION)
EASTERN DISTRICT OF MISSOURI)

I, Reginald L. Harris, Assistant United States Attorney for the Eastern District of Missouri, being duly sworn, do say that the foregoing information is true as I verily believe.

RLHarris
____

Subscribed and sworn to before me this 14th day of May 2015.

Gregory J. Linhares
CLERK, U.S. DISTRICT COURT

By: ______________________
DEPUTY CLERK